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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,897	04/06/2006	Augusto Amici	2503-1207	3387
466 7590 03/04/2010 YOUNG & THOMPSON 209 Madison Street Suite 500 Alexandria, VA 22314			EXAMINER BURKHART, MICHAEL D	
			ART UNIT 1633	PAPER NUMBER
			NOTIFICATION DATE 03/04/2010	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary

Application No.

10/574,897

Applicant(s)

AMICI ET AL.

Examiner

Michael Burkhardt

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/3/2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-26 is/are pending in the application.
- 4a) Of the above claim(s) 23-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/22)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date 4/6/2006.

DETAILED ACTION

Receipt and entry of the amendment dated 12/3/2009 is acknowledged. After entry of the amendment, claims 14-26 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Election/Restrictions

This application contains claims drawn to inventions nonelected with traverse in the reply filed on 5/13/2009. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Objections

Claims 14-22 are objected to for reciting non-elected subject matter, i.e. any SEQ ID NO: other than SEQ ID NO: 2.

Claim Rejections - 35 USC § 102

Claims 14-17 and 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al, (Cancer Res., 1998, cited by applicants). **This rejection is maintained for reasons made of record in the Office Action dated 9/3/2009, and for reasons set forth below.**

Response to Arguments

Applicant's arguments filed 12/13/2009 have been fully considered but they are not persuasive. Applicants essentially assert that: 1) the previous Office Action has interpreted the

claims to require the rat p185^{neu} only, rather than comprising a rat and human chimeric sequence as taught in the specification and illustrated in an appendix; 2) the rat/human chimeric proteins are useful in inducing immunity against tumors; 3) Chen et al fail to teach a chimeric rat human protein according to the instant claims.

Regarding 1) and 3), the claims have been amended to remove the "coding for a fragment" language but remain subject to an open interpretation. The instant claims are worded with open language, i.e. the vectors comprise "a nucleotide sequence" of SEQ ID NO: 2. The selection of "a nucleotide sequence" from SEQ ID NO: 2 appears arbitrary, and may include the entire sequence, or a portion of the sequence. The first ¶ of the specification teaches that the vectors of the invention may encode "different fragments of human or rat p185^{neu}." Hence, a DNA vector comprising the entire p185^{neu} rat gene is considered to be anticipatory of the claimed subject matter. Furthermore, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the claims are limited to a rat/human chimeric protein comprising the entirety of SEQ ID NO: 2) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Regarding 2), that an unclaimed protein encoded by the instant vectors has an intended use is not disputed at present. However, the bearing of this assertion on the instant rejection is unclear and not explained by applicants.

Claim Rejections - 35 USC § 103

Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al (Cancer Res., 1998, cited by applicants) in view of Krieg et al (U.S. patent 6,653,292).

This rejection is maintained for reasons made of record in the Office Action dated 9/3/2009, and for reasons set forth below.

Response to Arguments

Applicant's arguments filed 12/13/2009 have been fully considered but they are not persuasive. Applicants essentially assert that the claims 18 and 19 depend from claim 14, which is not anticipated by Chen et al, and Krieg et al do not make up the deficiencies of Chen et al.

Such is not convincing. Chen et al is not deemed to have any deficiencies for reasons set forth above. Hence, the rejection stands.

Double Patenting

Applicant is advised that should claim 21 be found allowable, claim 22 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). **This is a new warning necessitated by amendment of the claim dependency.**

Claim 21 recites a composition for parenteral administration, which by definition is an "injectable solution" as recited in claim 22. Thus, claim 22 does not appear to differ in scope from claim 21 in any meaningful way.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Burkhart whose telephone number is (571)272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Burkhart/
Primary Examiner, Art Unit 1633